

## **REMARKS**

In view of the Amendments set forth above and the remarks set forth below, Applicants respectfully request reconsideration and allowance of all pending claims 1-11 and 13-40.

### **35 U.S.C. 112 Rejections**

**Claims 11, 13-32, and 34 stand rejected under 35 U.S.C. 112, first paragraph, as purportedly failing to comply with the written description requirement.**

Applicants herein amend claim 11, 24, 20, 31, 32, and 34 to obviate this rejection.

**Claims 36-39 stand rejected under 35 U.S.C. 112, second paragraph, as purportedly failing to particularly point out and distinctly claim the subject matter that Applicants regard as their invention.** In particular, the Examiner states that it is unclear what is the intended meaning of the term “system” in the claim. Applicants traverse this rejection.

As set forth on page 5, first full paragraph and claims 33-37 as originally filed, among other sections of the present application, a system is defined as including an applicator (such as a spray applicator) and a composition. Applicants therefore submit that “system” is adequately defined and thus request reconsideration and withdrawal of this rejection to claims 36-39.

### **35 U.S.C. 102 Rejections**

**Claim 40 stands rejected under 35 U.S.C. 102 as being anticipated by Haslwanter et al. (U.S. Patent No. 5,854,269).** Applicants herein amend claim 40 to include 0.00001% to about 1.0% by weight of aloe barbadensis gel and 0.05% to about 5.0% by weight glycerin, which are nowhere taught by the reference cited by the examiner. As noted in the present application, glycerin facilitates maintaining some ingredients in an ionic state and the aloe acts as a soothing agent. None of these advantages are taught or suggested by the cited reference. Applicants therefore request reconsideration and allowance of claim 40.

Applicants note that the previous rejection to claims 1, 2, 11-15, and 27-29 under 35 U.S.C. 102(a) is withdrawn and that no further rejection to these claims (other than the

provisional rejection to claims 1, 11, and 29) is set forth in the present office action. Therefore, Applicants request a notice of allowance—at least with respect to claims 1, 2, 11-15, and 27-29.

### **35 U.S.C. 103 Rejections**

**Claims 3-10, 16-26, and 33-34 stand rejected under 35 U.S.C. 103 as being unpatentable over Davidson et al. in view of Haslwanter et al.** Applicants traverse this rejection.

First, Applicants submit that there is no suggestion or motivation in the references, to modify the cited references or to combine references' teachings. Davidson et al. discloses a method of applying a zinc ion gel to a nasal membrane. The composition has a viscosity and carrier configured to maintain the zinc ions in contact with the nasal membrane for an extended period of time. In contrast, Haslwanter et al. discloses an aqueous composition including oxymetazoline to treat nasal congestion. Haslwanter et al. does not teach or suggest applying the oxymetazoline via a viscous gel. Further, nothing in the reference suggests that maintaining the oxymetazoline in contact with a nasal membrane for an extended period of time has any benefit.

The Examiner asserts that a skilled artisan would be motivated to combine the references because both utilize menthol, which is desirable due to its ability to mask the odor of aromatic alcohols. Applicants disagree with this analysis. As stated by the Examiner, Haslwanter employs menthol for this purpose. But, Davidson et al. does not. Rather, Davidson et al. discloses that menthol can be used as an additional decongestant. Davidson et al. does not disclose any need for an aromatic alcohol or any need to mask the alcohol with menthol. It is further noted that, in the present application, menthol is defined as an aromatic compound, which is a decongestant, and is not used to mask other aromatic compounds. In other words, menthol is the aromatic compound, which has no need to be masked and cannot be masked by itself.

Second, no combination of the references teaches or suggests all the claim limitations. In particular, the combination does not teach or suggest “about 0.001 to about 5.0 weight percent of a decongestant selected from the group consisting of oxymetazoline hydrochloride, naphazoline hydrochloride, ephedrine, phenylephrine

hydrochloride, xylometaxoline hydrochloride, wherein the composition has a viscosity greater than about 2,500 centipoise,” as set forth in claim 1, from claims 3-10 depend. Neither reference discloses or suggests this particular viscosity limitation or a viscous composition containing these active ingredients. Accordingly, Applicants request reconsideration and withdrawal of this rejection to claims 3-10.

Similarly, no combination of the references teaches or suggests “about 0.000001 to about 10 weight percent an active substance selected from the group consisting of oxymetazoline hydrochloride, naphazoline hydrochloride, ephedrine, phenylephrine hydrochloride, and xylometaxoline hydrochloride, wherein the composition has a viscosity from about 3,000 centipoise to about 10,000 centipoise,” as set forth in claim 11, from which claims 16-23 depend. Applicants therefore request reconsideration and withdrawal of this rejection to claims 16-23.

Finally no combination of the references teaches or suggests “about 0.001 to about 1.0 weight percent of a decongestant comprising oxymetazoline hydrochloride... wherein the composition has a viscosity from about 2,500 centipoise to about 40,000 centipoise,” as set forth in claim 24, from which claims 25-26 depend. Applicants thus request reconsideration and withdrawal of this rejection to claims 24-26.

**Claims 30-31 stand rejected under 35 U.S.C. 103 as being unpatentable over Davidson et al. in view of Haslwanter et al., in further view of Pier (U.S. Patent No. 6,245,735).** Applicants respectfully traverse this rejection.

As noted above, there is no motivation to combine Davidson et al. and Haslwanter et al., there is no suggestion that the combination would be successful, and no combination of the references teaches or suggests all of the claimed elements. Further, there is no motivation to combine Pier with Davidson et al., Haslwanter et al. or the combination of the references.

Pier is directed to methods and products for upregulating cystic fibrosis transmembrane conductance regulators. Nowhere does Pier teach or suggest that liposomes are suitable in viscous cold remedy formulas including oxymetazoline hydrochloride.

Furthermore, no combination of the cited references teaches or suggests a permeation enhancer comprising liposomes as set for in both claims 30 and 31.

Moreover, no combination teaches or suggests “about 0.001 to about 5.0 weight percent of an active ingredient comprising oxymetazoline hydrochloride... wherein the composition has a viscosity between about 2,500 and about 40,000 centipoise,” as set forth in claim 30 or “about 0.001 to about 5.0 weight percent of an active ingredient comprising oxymetazoline hydrochloride... wherein the composition has a viscosity between about 2,500 and about 40,000 centipoise,” as set forth in claim 31. Applicants therefore request reconsideration and withdrawal of this rejection to claims 30 and 31.

**Claims 36-39 stand rejected under 35 U.S.C. 103 as being unpatentable over Davidson et al. in view of Haslwanter et al., in further view of Seidel et al. (U.S. 2001/0053775) or MacRae et al. (US 2002/0046751).** Applicants traverse this rejection.

As previously noted, there is no motivation to combine Davidson et al. and Haslwanter et al., there is no suggestion that the combination would be successful, and no combination of the references teaches or suggests all of the claimed elements. Further, there is no motivation to combine Seidel et al. or MacRae et al. with Davidson et al., Haslwanter et al. or the combination of the references.

Applicants submit that since no combination of these references teaches or suggests the composition of the system, and the addition of Seidel et al. and/or MacRae et al. does not cure this deficiency, Claims 36-39 are allowable over the cited references.

### **Double Patenting**

Claim 29 stands provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/664,839 and claims 1 and 11 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-29 and 34 of copending Application No. 11/028,991. Applicants acknowledge the Examiner’s assertion, but submit that no action is required at this time.

**Conclusion**

Applicants respectfully submit that all pending claims are now in condition for allowance and therefore respectfully request allowance of all claims. Should the Examiner have any questions regarding this Amendment and Response, the Examiner is invited to call the undersigned at the number provided below.

Respectfully submitted,

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